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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	) Box PCT
ÅKE LINDAHL et al.	)
Application No.: 09/700,177	) Attention: DO/EO/US
Filed: November 13, 2000	)
For: BIOLOGICALLY ACTIVE	) Group Art Unit: (unassigned)
COMPOSITION	)
	) Examiner: (unassigned)
	)
	)

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56,  
Applicants submit information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

Copies of the following items are provided:

- (1) "Enhancement of Percutaneous Absorption  
by the Use of Volatile: Nonvolatile  
Systems in Vehicles", M.F. Coldman et al.,  
J. Pharm. Sci., 58, No. 9, Pages 1098 to  
1102 (1969)  
[Discussed at Page 5 of Specification.]
- (2) "Polymer Films From Aqueous Latex Dispersions  
as Carriers for Transdermal Delivery of  
Lipophilic Drugs", Proceed. 15<sup>th</sup> Intern.  
Symp. Control Rel. Bioact. Material,  
Abstract No. 89, Pages 147 and 148, Basel (1998)  
[Discussed at Page 5 of Specification.]
- (3) East German Patent No. 217, 989  
Applicant: Ernst Moritz Arnd et al.  
Date: January 30, 1985.  
[Discussed at Page 5 of Specification.]

- (4) "Preparation and Dissolution Characteristics of Several Fast-Release Solid Dispersions of Griseofulvin", W.L. Chiou et al., J. Pharm. Sci., Vol. 58, No. 12, Pages 1505 to 1510 (1969).  
[Discussed at Page 5 of Specification.]
- (5) "Pharmaceutical Applications of Solid Dispersion Systems", W.L. Chiou et al., J. Pharm. Sci., Vol. 60, No. 9, Pages 1281 to 1301 (1971).  
[Discussed at Page 5 of Specification.]
- (6) "Polymer Films From Aqueous Latex Dispersions As Carriers for Enhanced Transdermal Delivery of Lipophilic Drugs - Influence of Drug-Polymer Interactions and Formulation Parameters On Release Characteristics", R. Lichtenberger et al., Conference Proceedings, IBC Technical Services Ltd. London, Pages 360 to 366 (April 1989)
- (7) "Transdermal Drug Delivery Systems" H.P. Merkle, Meth. And Find. Exp. Clin. Pharmacol., 11(3), Pages 150 to 151 (1989).
- (8) "Copolyester of Citric Acid and 1,2,6-Hexane Triol as a Matrix for Controlled Drug Release", D. Pramanick et al., J. Polymer Materials (13), Pages 173 to 178 (1996).

- (9) German Patent No. 4,400,770  
Applicant: LTS Lohmann Therapie-  
Systeme GmbH & Co KG  
Published: February 2, 1995  
[A drug contains plaster for the enhanced  
effect of estradiol. The plaster  
must contain an acid, such as citric  
acid, as a penetration enhancer in  
an amount of 0.01 to 20 percent. It is  
significant that the citric acid is  
unchanged and not reacted since its  
activity as a penetration enhancer  
is dependent on the acid form.]
- (10) European Patent Application No. 0430491  
"Transdermal Delivery Device for  
Estradiol and Process for  
Manufacturing Said Device"  
Applicant: LABORATORIES BETA S.A.  
Published: June 5, 1991

For the convenience of the Examiner a form PTOL-1449 is attached that lists the  
above items. Once these items are considered, it is requested that an Examiner-initialed  
copy of this form be returned to the undersigned.

Respectfully submitted,

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Filed: January 29, 2001

# INFORMATION DISCLOSURE CITATION

PTO-1449

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003300-696APPLICATION NO.  
New ApplicationAPPLICANT  
Åke LINDAHL et al.FILING DATE  
November 13, 2000GROUP  
Unassigned

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE

## FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	217 989	01-1985	DD				
	44 00 770	02/1995	DE				
	0 430 491	06/1991	EPO				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	M.F. Coldman et al., <i>Enhancement of Percutaneous Absorption by the Use of Volatile: Nonvolatile Systems in Vehicles</i> , J. Pharm. Sci., 58, No. 9, 1969, pp. 1098-1102
	Rainer Lichtenberger et al., <i>Polymer Films From Aqueous Latex Dispersing as Carriers for Transdermal Delivery of Lipophilic Drugs</i> , 15 <sup>th</sup> Int'l. Symp. Control Rel. Bioact. Material, Abstract No. 89, 1998, pp. 147-148
	W. L. Chiou et al., <i>Preparation and Dissolution Characteristics of Several Fast-Release Solid Dispersions of Griseofulvin</i> , J. Pharm. Sci., Vol. 58, No. 12, 1969, pp. 1505-1510
	W. L. Chiou et al., <i>Pharmaceutical Applications of Solid Dispersion Systems</i> , Vol. 60, No. 9, 1971, pp. 1281-1301
	Rainer Lichtenberger et al., <i>Polymer Films From Aqueous Latex Dispersions As Carriers for Enhanced Transdermal Delivery of Lipophilic Drugs - Influence of Drug-Polymer Interactions and Formulation Parameters on Release Characteristics</i> , Conf. Proceedings, IBC Tech. Svcs. Ltd., London, 1989, pp. 360-366
	H. P. Merkle, <i>Transdermal Drug Delivery Systems</i> , Meth. and Find. Exp. Clin. Pharama. 11 (3), 1989, pp. 150-151
	D. Pramanick et al., <i>Copolyester of Citric Acid and 1,2,6-Hexane Triol as a Matrix for Controlled Drug Release</i> , J. Polymer Materials (13), 1996, pp. 173-178

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.